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EXAMINER

MYERS, CARLA J

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

08/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ATTACHMENT TO ADVISORY:

Continuation of Box 3:

The proposed amendment filed after a final rejection will not be entered because the amendment raises new issues under 35 USC 112, first paragraph that require further consideration. The proposed amendment adds new claims 21-29. The claims as previously presented did not require the limitations set forth in claims 21-29, such as the limitation that the agent modulates binding of SFRP1 mRNA to a binding partner (claim 25) or that the agent modifies the SFRP1 mRNA to improve its stability or solubility (claim 29). In view of the new limitations set forth in the newly added claims, further consideration would be required. Additionally, the amendment to add new claim 29 raises the issue of new matter. The claim recites that the agent used in the screening methods is an agent that modifies SFRP1 mRNA to improve its stability or solubility. The response points to paragraph [0113] as providing support for this amendment. However, paragraph [0113] is not directed to agents to be used in screening assays. Rather, paragraph [0113] is directed to polynucleotides that have themselves been modified at the base moiety, sugar moiety or phosphate backbone to improve the stability, hybridization or solubility of the polynucleotide. Accordingly, the specification as originally filed does not appear to provide basis for the concept set forth in newly added claim 29 of a method comprising administering an agent to a mouse with lupus and determining if the agent modulates expression of the mouse SFRP1 mRNA, wherein the agent "modifies the mouse SFRP1 mRNA to improve its stability or solubility." The amendment to add new claim 21 also raises the issue of new matter.

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The reply points to paragraph [0175] as providing support for this amendment.

However, paragraph [0175] is directed to methods for the detection of specific polynucleotide molecules. This paragraph does not particularly address methods for detecting the expression level of SFRP1 mRNA. While the specification indicates that methods such as column chromatography and direct sequencing can be used to detect a specific polynucleotide sequence, these teachings do not provide support for the distinct concept of determining and comparing the expression of mouse SFRP1 mRNA (i.e., determining the quantity or level of mouse SFRP1 mRNA) by direct sequencing or column chromatography, as is encompassed by newly added claim 21. The amendment to add new claims 23 and 24 also raise the issue of new matter. While the specification provides support for the concept of an interfering RNA or a siRNA, the specification does not appear to provide support for the recitation that the agent is a ribozyme and that the ribozyme is an interfering RNA (claim 23) or an siRNA (claim 24). The amendment to add new claims 25-28 also raises the issue of new matter. While the specification provides support for the concept that an agent may be a small molecule or bioactive agent and for the concept of an agent that modulates the binding of SFRP to a binding partner, the specification does not appear to provide support for the concept that the agent is specifically an agent that modulates binding of SFRP1 mRNA to a binding partner. That is, the teachings in the specification cited by Applicants (para [0181-0183]) are directed to agents that are inhibitors of LRP proteins. These passages do not appear to be directed to agents that modulate SFRP1 mRNA.

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Accordingly, the specification also does not appear to provide support for newly added claims 25-28.

Continuation of Box 11:

The request for reconsideration has been considered but does not place the application in condition for allowance in view of the non-entry of the after final amendment. The arguments presented in the response of July 3, 2008 are limited to the claims as set forth in the after final amendment. In view of the non-entry of this amendment, these arguments are not persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carla Myers/

Primary Examiner, Art Unit 1634